REMARKS/ARGUMENTS

Claims 1, 6, and 8-12 have been amended. Claims 1-12 are pending. Applicant addresses the prior rejections in turn.

Indefiniteness Rejections

Without acquiescing to the rejections, the Applicant has amended claims 1, 6, and 8-12 in an effort to address the Examiner's concerns and to advance prosecution.

Claim 1: The preamble was amended as suggested by the Examiner thus resolving antecedent basis issue concerning the term "the heart." Antecedent basis issues concerning the terms "the external ventricular surface", "the lower surface", "the course", and "cardiac cycle" were resolved. The term "such that a hollow space exists between said sheet and the imaginary surface containing the perimeter of said sheet" was replaced with "to encompass a volume of space" (e.g., as shown in Fig. 3 and 4 and described in paragraph 105 in U.S. Patent App. Pub. No. 2008/0071133), thus resolving the antecedent basis issue concerning the terms "the volume" and "said space".

Claim 6: The preamble was amended as suggested by the Examiner thus resolving antecedent basis issue concerning "the heart" and "the left ventricle." Antecedent basis issues concerning "the external surface", "the peripheral margin", and "the external ventricular wall" limitations were resolved. The amended claim now includes additional limitations which resolve the antecedent basis issues concerning "the space" limitation.

Claim 8: Claim 8 now clarifies that the air-impermeable sheet is attached to the external ventricular wall during the end of a diastolic period of a cardiac cycle of the heart, which should be understood as an operational procedure of physically attaching the device to the heart, and that thereafter the air-impermeable sheet remains attached to the wall of the heart during all

cardiac phases and cycles. Claim 6 provides antecedent basis for "the external ventricular wall" limitation.

Claim 9: Claim 9 is amended to resolve antecedent basis issue concerning "the external ventricular surface" limitation.

Claim 10: Claim 10 is amended to resolve antecedent basis issue concerning "the external ventricular surface" limitation. The "fabric patch girdle" is described in Israeli patent application no. 154141, and in international patent application No. PCTI/IL04/000072 (WO 04/066805), referenced in paragraph 54 in U.S. Patent App. Pub. No. 2008/0071133.

Claim 11: Claim 11 is amended to resolve the antecedent basis issues concerning "the maximal value" and "the normally-outward expansive pressure" limitations. Claim 6 provides the antecedent basis needed for "the external ventricular wall" limitation.

Claim 12: Claim 12 is amended to resolve antecedent basis issues concerning "the ventricle" and "the left ventricle" limitations.

Applicants request withdrawal of the indefiniteness rejections.

Anticipation Rejections

Claims 1, 3, and 4 were rejected as allegedly anticipated by U.S. Patent No. 5,131,905 to Grooters (Grooters).

The device of claim 1 is not anticipated by Grooters's patent for at least the following reasons:

1) Grooters's device is designed to apply pressures on the wall of the heart by means of chambers included in the device itself.

2) Grooters's device is operated by means of EKG and pump means which inflate its chambers in timing with the cardiac cycle of the heart to which the device is attached.

3) Grooters's device is not designed, nor required, to be sealably attached to the wall of the heart and create a hollow space between the device and the heart wall.

4) Grooters's device is not designed, nor required, to apply radial outward normally directed forces on the wall of the heart to which it is attached.

5) Grooters's device is designed to encircle the entire perimeter of the heart and therefore it is not suitable for assisting a single ventricle.

As will be explained in detail, the device of claim 1 is designed to be attached over a specific heart ventricle and autonomously assist (i.e., not requiring any auxiliary EKG, pumps, control means, or the like) in the ventricle function by applying radial outward normally directed forces on the wall of the heart to which it is attached.

1) The chambers in Grooters's device

Grooters's device comprises a shell (30) having two internal membranes (31 and 32) -

> "[T]he device, or heart bag, of the present invention includes an outer flexible, non-distensible shell 30 having opposite inner and outer walls, a first distensible membrane 31 and a second distensible inner lining or membrane 32… so as to define an inflatable space 33 which can be filled with a liquid or gas through a supply hose 35." (Column 2, lines 49 to 56)

As shown in Figs. 4 and 7, further to inflatable space (33) a plurality of chambers (34, 36 and 38) are constructed between these internal chambers -

> "A plurality of chambers or compartments are formed between membrane 31 and inner membrane 32 where the membranes 31, 32 are not sealed to one another. More particularly, a first chamber 34 is formed on one side or end of device 10, while second and third chambers 36, 38 are formed in device 10 opposite chamber 34." (Column 2, lines 62-68)

Grooters's device is designed to assist a weak heart by inflating and deflating the chambers provided in it in synchronization with the cardiac contractions by using an EKG machine:

> "In use, device 10 is positioned on a weak or diseased heart… The heart 12 is operatively connected to an EKG machine (not shown) which senses the QRS waves of the heart to activate the pump for supplying fluid to compartments 34, 36 and 38 in timing with the contractions of the heart.". (column 3 lines 40-52)

The device of claim 1, however, is designed to operate autonomously due to sub-atmospheric pressure conditions evolving in the closed space obtained between the device and the wall of the heart to which it is attached.

2) Operation of Grooters's device

Grooters's device is designed to assist a weak heart by inflating and deflating the chambers provided in it in synchronization with the cardiac contractions. As cited above (column 3 lines 40-52), and immediately below, Grooters's device requires pump and EKG machines for operating the device and assisting the heart to which it is attached –

> "Each chamber is operatively connected to a fluid pump by fluid lines which allow fluid, either liquid or gas, to be rhythmically pumped into and out of the chambers to assist the systolic contractions of the heart. The device is operatively connected to an EKG machine which coordinates the pumping action in response to the QRS waves from the heart." (Column 2, lines 9-15)

As will be explained below, the device of claim 1 is designed to operate autonomously and it does not require any auxiliary means to assist in its operation.

3) Inflatable chambers/space in Grooters's device

As shown in Figs. 3, 4, 5, 6 and 7, the inflatable space (33) in Grooters's device is defined between non-distensible shell (30) and first distensible membrane (31). Further chambers are provided between the first distensible membrane (31) and the second (inner) distensible membrane (32):

> "A plurality of chambers or compartments are formed between membrane 31 and inner membrane 32…" (Column 2, lines 62-63)

It is thus clear that the inflatable space (33) and the chambers (34, 36 and 38) in Grooters's device are provided in the device itself. In Grooters's device there is no hollow space between the inner membrane (second distensible membrane 32) and the wall of the heart, since the inner membrane is designed for accommodating different heart sizes by adjusting the level of inflation of the inflatable space (33):

> "Space 33 can be inflated such that membrane 32 completely engages the heart, thereby allowing device 10 to be used on various sized hearts. For example, on a large heart, space 33 is collapsed and on smaller hearts, space 33 is inflated accordingly." (Column 2, lines 57-61)

The device of claim 1 in the present application does not include such inflatable chambers or space and it operates autonomously by means of a closed empty space obtained between the device and the wall of the heart to which it is attached.

4) Forces applied by Grooters's device.

As exemplified in Fig. 4 in Grooters's patent, Grooters's device is operated by filling its chambers with gas or fluid such that the inflated chambers assume an elliptic/oval cross-sectional shape, it is therefore clear that Grooters's device is not capable of exerting an outward and normally directed force on the external ventricular surface of the heart (*see, e.g.*, U.S. Patent App. Pub. No. 2008/0071133 at paragraph 119, illustrated in Fig. 8). Grooters's does not teach nor suggest exerting outward directed forces on the wall of the heart:

> "The chambers are actively deflated shortly after inflation to allow the heart to fill and be ready for the next contraction." (Column 2, lines 15-17)

Namely, Grooters's device is designed to apply only radial inwardly directed compressive forces, and the deflation of the chambers does not apply any forces over the heart

wall, and in any case the chamber design in Grooters's device is not suitable for applying radial outward directed forces as obtained with the device of claim 1.

5) Device structure

As shown and described (Figs. 1, 3, 6 and 7, column 3 lines 14-17) Grooters's device is configured to enclose the entire perimeter of the heart in order to apply compressive forces over the left and right ventricles. This configuration is substantially different from that of the device of claim 1 in the present invention which is designed to be placed over a wall region of the heart for covering a single ventricle.

Furthermore, as indicated in Grooters's patent "the membranes 31, 32 are not sealed to one another" (Column 2, line 64), such that the chambers provided in Grooters's device are designed to be inflated concurrently. Accordingly, Grooters's device is not capable of applying forces over the left ventricle only, which is an important feature of embodiments of the presently claimed device:

> "The device of the present invention is based on uniquely applying a Normally directed, outward expansive force or pressure (force per unit area), which is evenly distributed on the wall region of the left ventricle, in order to reduce the intraluminal hydrostatic pressure of the left ventricle, also known as LV filling pressure…" (U.S. Patent App. Pub. No. 2008/0071133, paragraph 86)

> "[A]n important objective of the present invention is to significantly reduce the hydrostatic pressure in the left ventricle during the diastolic stage of the cardiac cycle, thereby, improving diastolic function of the left ventricle of the heart, while minimally disturbing systolic function of the heart" (*Id.*, paragraph 88)

The device of the present invention is designed to autonomously react to the ventricular changes of the heart during the cardiac cycles, thus not requiring pumps, EKG machine, or any other auxiliary devices as used in the prior art publications:

> "[S]aid at least one air-impermeable sheet is capable of creating a sub-atmospheric pressure within said closed empty space as a consequence of changes in the volume of said space during the course of the cardiac cycle, thereby exerting an outward and normally directed force on the external ventricular surface of the heart…" (*Id.*, paragraph 36)

This may be achieved by the device of claim 1 due to the hollow space provided by the device (12 in Fig. 3, and as described in paragraph 105 in U.S. Patent App. Pub. No. 2008/0071133) and by sealing the contact surface between the device and the wall of the heart to which it is attached:

> "In order to achieve a negative or sub-atmospheric pressure, the contact surface between the device and the cardiac surface needs to be sealed, or partially sealed, to prevent loss of pressure." (*Id.*, paragraph 92)

Claim 1 defines a device for assisting ventricular function of the left or right ventricle utilizing curved/angled air-impermeable sheet designed to be attached over the wall of the heart and assist the ventricular function by:

> "[C]reating a sub-atmospheric pressure within said closed empty space as a consequence of changes in the volume of said space during course of cardiac cycle of said heart, thereby exerting an outward and normally directed force on said external ventricular surface of the heart to which said air-impermeable sheet may be connected by means of said one or more connecting elements" (claim 1)

As explained in details above Grooters's device is not designed, nor intended, to provide a closed empty space between the device and the wall of the heart to which it is attached, and it is not capable of operating autonomously as the device of claim 1. Grooters's patent does not teach nor suggests these features of the device of claim 1, the device described in it is not capable of applying outward normally directed forces, and it is not designed to cover a single ventricle to be treated.

Claim 3: Grooters's patent particularly specifies that its device comprises a flexible non-distensible shell:

> "The device includes a flexible, non-distensible shell." (Column 2, line 3)
>
> "[T]he device, or heart bag, of the present invention includes an outer flexible, non-distensible shell 30…" (Column 2, lines 48-50).

It is thus clear that the shell in Grooters's device is essentially flexible but not expandable. Grooters's patent does teach nor suggest adding to the flexible shell elements for increasing its rigidity.

Claim 4: Grooters's patent particularly specifies that the membranes provided in the shell of the device are distensible shells:

> "[N]on-distensible shell 30 having opposite inner and outer walls, a first distensible membrane 31 and a second distensible inner lining or membrane 32 secured to the first membrane 31… Membrane 31 is secured to shell 30 around the upper perimeter edge of the shell so as to define an inflatable space 33… " (Column 2, lines 49-55)

Accordingly, the membranes in Grooters's device are distensible elements which are used for providing the inflatable space (33) and chambers (34, 36 and 38), and as such they are not intended, nor required, to add rigidity to the device.

Obviousness Rejections

Claim 2 was rejected as allegedly unpatentable over Grooters in view of U.S. Patent No. 4,690,134 to Snyders (Snyders). Claims 5-8 and 11-12 were rejected over Grooters in view of U.S. Patent App. Pub. No. 2004/0267086 to Anstadt et al. (Anstadt) Claim 9 was rejected over Grooters in view of Anstadt and Snyder. And claim 10 was rejected over Grooters in view of Anstadt and U.S. Patent No. 5,702,343 to Alferness (Alferness). Applicants request withdrawal of these rejections, in light of the above comments with respect to Grooters as well as the below

comments regarding the additional references. The rejections are addressed in order of claim number.

Claim 2: As explained above, the subject matter of claim 1 is not obvious in view of Grooters. Though prima facie the use of biocompatible polymeric materials in medical devices might not be an inventive subject matter (Applicant has no opinion one way or another on the matter), neither Grooters nor Snyders, separately or in combination, teach or suggests attaching a curved biocompatible polymeric air-impermeable sheet to the wall of the heart as set forth in claim 2.

Claim 5: Though Anstadt's device may include a one-way valve the cup-shaped shell used in this device is operated utilizing sensors (sensor 1210 Figs. 6 and 7) and control means (control unit 1222 Fig. 6C) adapted to regulate the flow of the inflation fluid used for compressing the heart:

> "Other aspects of DMVA Cup 103 of FIG. 6A are similar to other DMVA Cups described in this specification, and include… liner inflation/deflation duct 120; working fluid as indicated by phantom arrows 197 shown flowing into the space between shell 110 and liner 114, thereby inflating liner 114 and compressing heart 30; and seal 113." (Anstadt, paragraph 365)

Accordingly, Anstadt's device is not capable of operating autonomously and it is not designed to apply normally outward directed forces over the wall of the heart to which it is attached. The cup-shaped shell of Anstadt's device essentially encircles the entire circumference of the heart and it is not capable of operating on one ventricle only. It is therefore clear that Anstadt's device is not designed to be attached over a selected ventricle of the heart, and that it is not capable of operating autonomously according to the cardiac state of the heart to which it is attached. As explained above, Grooters's device is also operated utilizing auxiliary means

(pump and EKG machines) and it is thus understood that the teaching of Anstadt and Grooters do not teach nor suggest, separately or in combination, an autonomous ventricular function assisting device comprising a one-way valve, as claimed in claim 5.

Claim 6: Grooters describes attaching a flexible non-distensible shell to an external surface of a heart, however, Grooters does not teach nor suggests ascertaining air-tight sealing of a peripheral margin of the flexible non-distensible shell to the external ventricular wall. As explained in details hereinabove, Grooters's device comprises inflatable space and chambers which are used for applying inward directed compressive forces in timing with the cardiac cycle by means of a pump and EKG machines, such that air-tight sealing is not required for its operation.

Amended claim 6 now includes the following additional recitations:

> "said air-impermeable sheet is curved or angled to encompass a volume of space"
>
> "such that an outward and normally directed force may be exerted on the external ventricular surface of the heart due to changes in the volume of said space during the course of cardiac cycle of said heart"

The description of Anstadt and Grooters do not teach nor suggest, separately or in combination, attaching a curved/angled air-impermeable sheet to the external ventricular wall, ascertaining air-tight sealing of the sheet over the ventricular wall such that an outward and normally directed force may be exerted over it due to changes in the volume of the space obtained between the sheet and ventricular wall during the course of cardiac cycle of said heart.

Claim 7: Applicants request withdrawal of the obviousness rejection of claim 7 for at least the same reasons set forth above with respect to claim 5.

Claim 8: Amended claim 8 recites that the air-impermeable sheet is attached to the external ventricular wall during the end of a diastolic period of a cardiac cycle of the heart. Thereafter, the device remains attached to the wall of the heart during all cardiac phases and cycles. An advantage in attaching the device to the heart during the end of a diastolic period may be related to the special principle of operation of the device, as it is designed to build sub-atmospheric pressure in the closed space obtained between the device and wall of the heart to which it is attached during the systolic contraction:

> "During systolic contraction of the ventricle, the volume of the internal space, between the device and the ventricular surface, enlarges. Since P*V is constant, when V enlarges, P decreases, thus creating normally directed forces, or a negative pressure." (U.S. Patent App. Pub. No. 2008/0071133 at paragraph 104)

As explained above, Grooters's device is designed to "be used on various sized hearts" (Grooters, column 2, lines 57-59), it is however not intended, nor required, to be attached to the heart during the end of a diastolic cycle of the heart, since it is designed to encircle the entire heart perimeter and apply compressive forces over its ventricles by means of auxiliary means (pump and EKG machines), such that its chambers are deflated during the diastolic cycle.

Claim 9: As explained above, the subject matter of claim 6 is not obvious in view of Grooters and/or Ansstadt, taken separately or in combination. Moreover, neither Grooters, Anstadt or Snyder, taken separately or in combination, teach or suggests the use of transmural biocompatible pins, non-transmural pins, biocompatible needles, biocompatible spikes, biocompatible helical coil screws, biocompatible clamps, biocompatible tubes, or biocompatible glue and surgical sutures, for attaching a curved air- impermeable sheet to the wall of the heart, as in claim 9.

Claim 10: As the Examiner indicated, the girdle construction of Alferness is a cardiac CRD jacket which is designed to surround the heart circumference:

> "In another embodiment, a cardiac reinforcement device is a biomedical material shaped as a jacket with a predetermined size selected for the jacket to surround the epicardial surface of the heart and circumferentially constrain cardiac expansion." (Column 1 line 66 to column 2 line 3)
>
> "FIG. 3 is a perspective view of one embodiment of a CRD jacket 15 according to the invention." (Column 6, lines 29-30)

Alferness's cardiac CRD jacket is thus a device which encircles the heart and it is not suitable for attaching the air-impermeable sheet used in the device of the present invention, and it is not suitable for ascertaining air-tight sealing, to the external ventricular wall.

As explained hereinabove, the fabric patch girdle recited in claim 10 for attaching the air-impermeable sheet to the external ventricular wall is referenced in WO 04/066805 (paragraph 54 in U.S. Patent App. Pub. No. 2008/0071133). This fabric patch girdle is a connecting element capable of being attached to the external surface of the ventricular wall:

> "One such type of connecting element is the cardiac girdle depicted in FIG. 11. As shown in FIG.. 11A, the cardiac girdle 40 comprises a thin patch 42 which may be attached to the external surface of the ventricular wall." (WO 04/066805 page 43 lines 7-10)

It is therefore clear that the subject matter of claim 10 is not obvious in view of Grooters, Anstadt, and/or Alferness, taken separately or when combined.

Claim 11: As explained above, the subject matter of claim 6 is not obvious in view of Grooters and/or Anstadt, taken separately or in combination. Anstadt teaches applying pressure condition of up to 20 mm Hg (paragraph 362), however the pressure in Anstadt's device is applied by means of a DMVA drive unit (1310) employing control and sensor means. Accordingly, Grooters and/or Anstadt, taken separately or combined, do not teach nor suggests

the method of claim 11 wherein expansive pressure having a maximal value in a range of about 5 mm Hg to about 40 mm Hg are applied using the method of claim 6.

Claim 12: As explained above, the subject matter of claim 6 is not obvious in view of Grooters and/or Anstadt, taken separately or in combination. Accordingly, claim 12 defining a method for autonomously improving diastolic ventricular function of the left ventricle is also not obvious in view of Grooters and/or Anstadt.

All claims are believed to be in good condition for allowance. If any small matter remains outstanding (e.g., that may be resolved with an Examiner's Amendment), the Examiner is encouraged to telephone Applicant's representative. Prompt reconsideration and allowance of this application is requested.

The Commissioner is hereby authorized to charge any deficiency , or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140

Respectfully submitted,

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